

<b>Interview Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/841,025	ARONHIME ET AL.
	Examiner Celia Chang	Art Unit 1625

All participants (applicant, applicant's representative, PTO personnel):

(1) Celia Chang. (3) \_\_\_\_\_.

(2) King Wong. (4) \_\_\_\_\_.

Date of Interview: 05 July 2006.

Type: a) Telephonic b) Video Conference  
c) Personal [copy given to: 1) applicant 2) applicant's representative]

Exhibit shown or demonstration conducted: d) Yes e) No.  
If Yes, brief description: \_\_\_\_\_.

Claim(s) discussed: newly proposed.

Identification of prior art discussed: RN371165036-5 and 371165-43-4.

Agreement with respect to the claims f) was reached. g) was not reached. h) N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Applicants presented proposed amendments in form of claiming the products by their registered chemical names by CAS as provided by the examiner. Applicants must verify that the CAS registered compounds are identical to the products described in the disclosure.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

  
Examiner's signature, if required

## **Summary of Record of Interview Requirements**

### **Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record**

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

### **Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews**

#### **Paragraph (b)**

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

#### **37 CFR §1.2 Business to be transacted in writing.**

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,  
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

#### **Examiner to Check for Accuracy**

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

AN 2001:798053 CAPLUS  
 DN 135:348889  
 TI Zolpidem hemitartrate polymorphs for treatment of insomnia  
 IN Aronhime, Judith; Dolitzky, Ben-Zion; Kordova, Marco; Leonov, David;  
     Meszaros-Sos, Erzebet; Salyi, Szabolcs; Schwartz, Anchel; Szabo, Csaba;  
     Zavurov, Shlomo  
 PA Teva Pharmaceutical Industries Ltd., Israel; Teva Pharmaceuticals USA,  
     Inc.  
 SO PCT Int. Appl., 58 pp.  
 CODEN: PIXXD2  
 DT Patent  
 LA English  
 FAN.CNT 1

	PATENT NO.	KIND	DATE	APPLICATION NO.	DATE
PI	WO 2001080857	A1	20011101	WO 2001-US13175	20010424
	WO 2001080857	C2	20020627		
	W: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW RW: GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW, AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR, BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG				
	CA 2406982	AA	20011101	CA 2001-2406982	20010424
	AU 2001057213	A5	20011107	AU 2001-57213	20010424
	US 2002077332	A1	20020620	US 2001-841025	20010424
	EP 1292304	A1	20030319	EP 2001-930705	20010424
	EP 1292304	B1	20051102		
	R: AT, BE, CH, DE, DK, ES, FR, GB, GR, IT, LI, LU, NL, SE, MC, PT, IE, SI, LT, LV, FI, RO, MK, CY, AL, TR				
	JP 2003531173	T2	20031021	JP 2001-577956	20010424
	NZ 522015	A	20040827	NZ 2001-522015	20010424
	EP 1473036	A1	20041103	EP 2004-10435	20010424
	R: AT, BE, CH, DE, DK, ES, FR, GB, GR, IT, LI, LU, NL, SE, MC, PT, IE, SI, LT, LV, FI, CY, TR				
	EP 1475093	A1	20041110	EP 2004-10651	20010424
	R: AT, BE, CH, DE, DK, ES, FR, GB, GR, IT, LI, LU, NL, SE, MC, PT, IE, SI, LT, LV, FI, CY, TR				
	CN 1592621	A	20050309	CN 2001-811697	20010424
	EP 1541146	A1	20050615	EP 2005-1922	20010424
	R: AT, BE, CH, DE, DK, ES, FR, GB, GR, IT, LI, LU, NL, SE, MC, PT, IE, SI, LT, LV, FI, CY, TR				
	DE 20122436	U1	20051020	DE 2001-20122436	20010424
	DE 20122435	U1	20051110	DE 2001-20122435	20010424
	AT 308324	E	20051115	AT 2001-930705	20010424
	EP 1600159	A1	20051130	EP 2005-16275	20010424
	R: AT, BE, CH, DE, DK, ES, FR, GB, GR, IT, LI, LU, NL, SE, MC, PT, IE, SI, LT, LV, FI, CY, TR				
	EP 1604663	A1	20051214	EP 2005-16276	20010424
	R: AT, BE, CH, DE, DK, ES, FR, GB, GR, IT, LI, LU, NL, SE, MC, PT, IE, SI, LT, LV, FI, RO, MK, CY, AL, TR				
	ES 2248321	T3	20060316	ES 2001-1930705	20010424
	ZA 2002008454	A	20031020	ZA 2002-8454	20021018
	US 2004214858	A1	20041028	US 2004-852912	20040524
	US 2004214859	A1	20041028	US 2004-853640	20040524
	US 2004220210	A1	20041104	US 2004-853031	20040524
	US 2004220211	A1	20041104	US 2004-853033	20040524
	US 2004220212	A1	20041104	US 2004-853338	20040524
	US 2004220213	A1	20041104	US 2004-853345	20040524
	JP 2006137778	A2	20060601	JP 2006-33099	20060209

PRAI	US 2000-199298P	P	20000424
	US 2000-206025P	P	20000522
	US 2000-225364P	P	20000814
	EP 2001-930705	A3	20010424
	JP 2001-577956	A3	20010424
	US 2001-841025	A3	20010424
	WO 2001-US13175	W	20010424

**AB** The present invention provides for novel polymorphs of zolpidem hemitartrate and the preparation of the polymorphs. The zolpidem hemitartrate are prepared as hydrates or solvates, e.g., zolpidem hemitartrate methanolate or acetone. For example, 5 g (17.7 mmol) of zolpidic acid was suspended in 50 mL of toluene and 0.15 mL of DMF and the mixture was cooled to 15-28°. Then, 1.7 mL (23.3 mmol) of thionyl chloride was added into the mixture at this temperature for 1 h, then it is stirred for 4 h

at 35-40°. After formation of acid chloride the thionyl chloride excess was removed by distillation. The volume of the reaction mixture was adjusted

to 50 mL by toluene, then it was cooled to -5-0°, and dimethylamine gas was introduced into the reaction mixture until the pH was 8.5-9.5. Precipitation of zolpidem base started almost immediately. The suspension was cooled to -10-(-12)° and mixed for 1 h. The crude product was filtered and washed consecutively with toluene, 5% cooled water solution of NH<sub>4</sub>CO<sub>3</sub> and cooled water. The product was dried under vacuum to obtain 4.1 g (yield 80%) zolpidem base used in preparation of hemitartrate polymorphs.

**IT** 371165-36-5P 371165-43-4P

RL: BAC (Biological activity or effector, except adverse); BSU (Biological study, unclassified); PRP (Properties); SPN (Synthetic preparation); THU (Therapeutic use); BIOL (Biological study); PREP (Preparation); USES (Uses)

(preparation and characterization of zolpidem hemitartrate polymorphs for insomnia treatment)

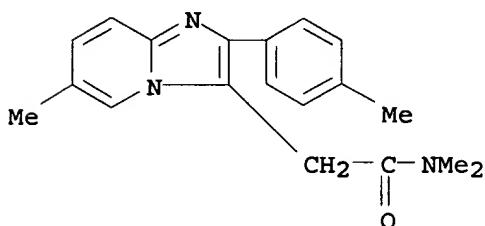
**RN** 371165-36-5 CAPLUS

**CN** Imidazo[1,2-a]pyridine-3-acetamide, N,N,6-trimethyl-2-(4-methylphenyl)-, (2R,3R)-2,3-dihydroxybutanedioate (2:1), dihydrate (9CI) (CA INDEX NAME)

CM 1

CRN 82626-48-0

CMF C19 H21 N3 O

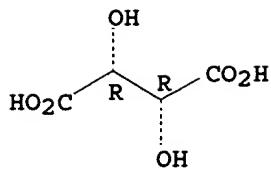


CM 2

CRN 87-69-4

CMF C4 H6 O6

Absolute stereochemistry.



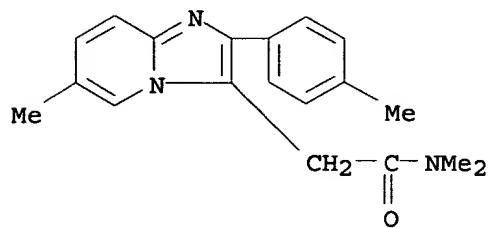
RN 371165-43-4 CAPLUS

CN Imidazo[1,2-a]pyridine-3-acetamide, N,N,6-trimethyl-2-(4-methylphenyl)-, (2R,3R)-2,3-dihydroxybutanedioate, compd. with ethanol (2:1:1) (9CI) (CA INDEX NAME)

CM 1

CRN 82626-48-0

CMF C19 H21 N3 O

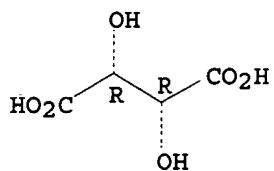


CM 2

CRN 87-69-4

CMF C4 H6 O6

Absolute stereochemistry.



CM 3

CRN 64-17-5

CMF C2 H6 O

H<sub>3</sub>C—CH<sub>2</sub>—OH

RE.CNT 3 THERE ARE 3 CITED REFERENCES AVAILABLE FOR THIS RECORD  
ALL CITATIONS AVAILABLE IN THE RE FORMAT